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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,781	05/04/2001	Michael Snyder	2493.0010002/RWE/JKM	9891

26111 7590 06/29/2007  
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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

MAIL DATE DELIVERY MODE

06/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/849,781

Applicant(s)

SNYDER ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188, 192-195 and 198 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, 181-186, 188 and 192-198.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12-16, 93-101, 106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, 175 and 196-197 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, 181-186, 188, 192-198 .

**DETAILED ACTION**

***Election/Restrictions***

Newly submitted claims 196-198 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are drawn to distinct invention of recombinant or fusion proteins, which have not been examined in the last Office action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 196-197 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claims Status***

Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, 181-186, 188, and 192-198 are pending.

Claims 12-16, 93-101, 106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, 175 and 196-197 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim.

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Claims 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188, 192-195 and 198 are under consideration in this Office Action.

***Withdrawn Objection and Rejections***

In view of applicants' amendments to claim 193, the objection has been withdrawn. Also, the 35 USC 103 over Wagner has been withdrawn in view of applicants' arguments.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188, 192-195 and 198 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed array comprising of different substances comprising 61 kinases from mammal, yeast and *Drosophila* would read on a naturally occurring array i.e., mammals inherently containing enzymes as kinases. The naturally occurring kinase present in mammals bound to a membrane reads on the claimed solid support.

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Furthermore, there is no utility in simply collecting known compounds and positioning the known compounds in an array, as claimed.

***Claim Rejections - 35 USC § 112***

Claims 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188, 192-195 and 198, as added, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection).

The claimed "comprises 61 kinases" is not supported in the as-filed specification. In the amendment of 11/8/2004, applicants amended the claims to contain this limitation. Applicants however failed to specifically point out where in the specification support for the new limitations can be found. See MPEP 714.02. Also, the newly added claim 198 is not supported in the as-filed specification.

MPEP § 2163.05 states "[t]he failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation or to

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use claim language which is not synonymous with the terminology used in the original disclosure"

Claims 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188, 192-195 and 198, as added, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for yeast protein' kinases of the Ser/Thr and tyrosine kinase family, does not reasonably provide enablement for the broad scope of an array of 61 kinases and functional domain kinase from an organism as mammal, yeast or Drosophila. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed array comprises a broad genus of compositions. The claimed different substances encompass any members of the protein kinase from the organism of 'mammal, yeast, or Drosophila' which is broader than the enabling disclosure. The claimed array represents enormous scope because the claims do not place any limitations on the kind, number and/or length of kinase either singly from one family of organism or a combination(s) from the different numerous recited organisms. The instant specification is directed to an array comprising a plurality of different yeast protein kinase, specifically 122

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different yeast protein' kinases of the Ser/Thr and tyrosine kinase family members (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). The specification does not provide reasonable assurance to one skilled in the art that the 61 kinases found in the yeast could be found in any or all of the organisms such as mammals especially the functional domain thereof. It is not apparent from the specification whether the same number of kinases or the kind of kinases or functional domain thereof can be found in any other organisms and made into an array. It is not apparent from the disclosure as to the functional domain of the kinase and the specific function attributed to said kinase positioned on the array. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. In a highly unpredictable art, as biotechnology, where one cannot predict whether one species would be predictive to the huge scope of the claimed, one cannot make a priori statement without any experimental studies. Factors such as the compatibility of the array with the substrate and compounds disposed therein, the compounds disposed in the array and other unpredictable variables can affect the function of the compounds. Thus, one



cannot predict from a single species its correspondence or extrapolation to the genus, as claimed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188, 192-195 and 198 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is indefinite as to what determines a 61 kinase in one organism, let alone, in a plurality of organisms have 61 kinase especially the functional kinase domain of said kinase. It is unclear whether the 61 kinase is present in one array or each spot in an array comprises 61 kinase each from different microorganisms. Clarification/explanation is required. The metes and bounds of the claimed "functional kinase domains" is not clearly set forth in the specification. There is no differentiating feature(s) of a functional domain from the non-

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functional ones given no structure for any kinase of any organism specifically mammals.

B. Claim 1 is indefinite for improper Markush claiming or grouping of the generic organisms mammal and the species, yeast and Drosophila.

C. Claim 198 is unclear as to the recited "domains retain kinase activity". Does positioning the kinase in an array can result in loss of kinase activity?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1-11, 141, 181-186, 188, and 192-195 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Uetz et al (Nature, 2/10/2000). (Based on the claimed interpretation of kinase present in a single organism and positioned in an array).

Uetz et al, throughout the reference, teach a protein array representing yeast genome encoded proteins (see Abstract of the reference). The reference teaches fusing roughly 6000 potential ORFs (genes) from yeast genome (which comprises approximately 6000 genes) (see page 623, left col., 1st paragraph. and page 624, left col., 2<sup>nd</sup> paragraph). Uetz teaches the yeast proteins were expressed in 96-well assay plates (page 624, left col., bottom of 2nd paragraph), which reads on a solid support of the addressable array of claim 1 because each well of the plates would have defined (or addressable positions). The reference also teach each of the protein encoded by a gene is expressed individually in individual wells of the plates as shown in Figure 1 of the reference (page 624), which reads on each protein being at a different position on a solid support of claim 1, for example. The claimed kinase present in the array would have been inherent to the yeast array taught by Uetz since yeast inherently contain kinase in its structure or would have

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been obvious to determine given the identified genome of yeast as taught by Uetz.

Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); *In re Best* 195 USPQ 430 (CCPA 1977).

Claims 1-11, 141, 181-186, 188, and 192-195 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon (WO 95/35505) in view of Felder et al (USP 6458533) or Lafferty(USP 6972183).

Shalon discloses at e.g., page 12, lines 3-9:

A microarray as an array of regions having a density of discrete regions of at least about 100/cm<sup>2</sup>, and preferably at least about 1000/cm<sup>2</sup>. The regions in a microarray have typical dimensions, e.g., diameters, in the range of between about 10-250  $\mu$ m, and are separated from other regions in the array by about the same distance.

Shalon discloses at e.g., page 30, line 30 up to page 32, line 15:

Sheets of plastic-backed nitrocellulose where each microarray could contain, for example, 100 DNA fragments representing all known mutations of a given gene. The region of interest from each of the DNA samples from 96

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patients could be amplified, labeled, and hybridized to the 96 individual arrays with each assay performed in 100 microliters of hybridization solution..... In addition to the genetic applications listed above, arrays of whole cells, peptides, **enzymes**, antibodies, antigens, receptors, ligands, phospholipids, polymers, drug cogener preparations....

Shalon discloses an array of enzymes and not kinase as claimed. However, Feder discloses:

Feder discloses at Example 18:

Kinases are enzymes that attach a phosphate to proteins. Many have been shown to stimulate normal and neoplastic cell growth. Hence, compounds that inhibit specific kinases (but not all kinases) can be used to test whether the kinases are involved in pathology and, if so, to serve as starting points for pharmaceutical development. For example, five tyrosine kinases that are involved in stimulating cell growth or in regulating the inflammatory response are src, lck, fyn, Zap70, and yes. Each kinase has substrates that are partially identified, as short peptides that contain a tyrosine. Some of the kinase specificities overlap so that different kinases may phosphorylate some peptides equally but others preferentially. For the five kinases, 36 peptide substrates are selected that show a spectrum of specific and overlapping specificities.

Lafferty discloses at e.g., col. 31, lines 41-49 the conventionality of an array containing substrate-enzymes such as kinase.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use in the array of Shalon the enzyme kinase as taught by Feder. Feder teaches that kinase have been shown to stimulate

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normal and neoplastic cell growth. To use the kinase in the array of Shalon would lead one having ordinary skill in the art in determining the kinase in the array responsible for neoplastic or normal cell growth. Furthermore, as taught by Lafferty an array containing a kinase is known in the art. [See also applicants' admission in the response at page 17, of the 12/19/2006 REMARKS. Applicant states: compositions **utilizing well-known and well-characterized classes of proteins**, as in the presently claimed invention].

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, for example, is provisionally rejected on the ground of nonstatutory double patenting over claims 1, for example of copending Application No. 10/477329 ('329 application). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the '329 claims disclose the same array as the instant array except the '329 claims do not claim the kinase array as instantly claimed. However, the disclosure of the '329 application discloses said array with kinase.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

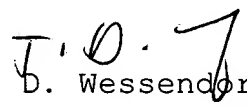
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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw  
June 21, 2007